

Congress of the United States
House of Representatives
Washington, DC 20515

June 2, 2022

The Honorable Maria Cantwell
Chairwoman
Senate Commerce Committee
511 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Roger Wicker
Ranking Member
Senate Commerce Committee
555 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairwoman Cantwell and Ranking Member Wicker,

As you weigh the many different priorities to be included in the negotiated COMPETES Act, we urge you to include the provisions of the bipartisan *Continuous Manufacturing Research Act* (H.R. 3851) that authorize the National Science Foundation to invest in research on advanced pharmaceutical manufacturing techniques that would improve our domestic production of generic medicines, reduce drug shortages, and restore America's position as a global leader in health care innovation. HR 3851 was included in the National Science Foundation for the Future Act which overwhelmingly passed the House in June 2021.

Shortages of essential generic drugs have been a persistent problem in our health care system for years. Most generic drugs are cheap to make and sell, meaning there is little margin for manufacturers to invest in modern manufacturing technology or redundant operations. The slightest delay or stoppage in manufacturing at one plant can result in nationwide drug shortages that frustrate providers, compromise patients' access to care, and expose consumers to price gouging by unscrupulous manufacturers. Additionally, our reliance on foreign suppliers located in China and other hostile nations for essential medicines and the ingredients necessary to make those medicines is a national security risk.

In the U.S., most generic drugs are manufactured in a "batch production" process that hasn't changed since the 1950s. In this model, engineers process large "batches" of material at each stage of the production process. Engineers can only undertake quality control after a batch is finished. If the quality is not satisfactory, the entire batch must be discarded, and the process begins again from the start.

By comparison, a continuous manufacturing model is an emerging technology whereby a finished pharmaceutical is produced in a steady stream, much like a traditional assembly line. This approach allows for chemical engineers to precisely control product quality, quickly identify any production problems, and minimize waste and discharge. It also reduces production costs for the manufacturer, increasing the margin on a generic drug and improving the incentive to invest in the sector.

Our reliance on outdated batch manufacturing techniques for essential generic medicines increases the costs of production, puts us at a disadvantage against international competitors, and makes quality failures at plants more likely. Unfortunately, the low prices and thin margins manufacturers get for essential generic medicines have stymied private investment in expanding and developing modern production techniques like continuous manufacturing.

Last year, we were proud to introduce the bipartisan *Continuous Manufacturing Research Act* (H.R. 3851) to authorize the National Science Foundation to invest in research on advanced pharmaceutical manufacturing techniques like continuous manufacturing. These investments would provide much-needed assistance to continuous manufacturing programs by supporting research, workforce development, and more. Additionally, the bill would authorize grant funding for students pursuing a degree in pharmaceutical engineering.

Investments in ensuring patients and providers have access to the drugs they need to stay healthy are commonsense and have strong bipartisan support. We urge you include the key provisions of the *Continuous Manufacturing Research Act* in the final conferenced agreement, consistent with what already passed the U.S. House.

Thank you very much for your consideration.

Sincerely,



Abigail D. Spanberger
Member of Congress



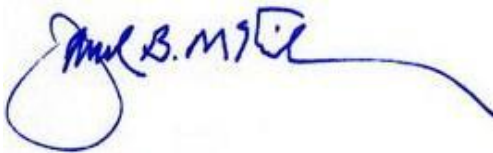
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